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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,305	10/27/2004	Lionel Breton	112701-434	6006
29157 7590 12/20/2007 BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 12/20/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/505,305	<b>Applicant(s)</b> BRETON ET AL.	
	<b>Examiner</b> Irene Marx	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/30/07.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 11-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 25-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

Claims 1-10 and 25-30 are being examined to the extent that they are directed to a bacterial culture only.

Claims 11-24 are withdrawn from consideration.

The rejection under 35 U.S.C. 112, first paragraph regarding deposit is withdrawn in view of applicant's averments..

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the it is unclear whether the percentage by weight now recited pertains to each of the at least one probiotic lactic acid bacterium and at least one the carotenoid or to both together.

Also, the phrase "at least one carotenoid or derivative" is not particularly defined in the specification. It is noted that at page 15, paragraph 5 applicant provides some examples of carotenoids and points out some sources of such carotenoids. However, it is not clear which compounds are encompassed "carotenoid derivatives" in this context.

To clarify the invention, it is recommended that claims 1 and 4 be amended to recite "Lactobacillus" and "Bifidobacterium", which are the art accepted designations for the genera involved.

Claim 4 is confusing in lacking antecedent basis in claim 3, in that there are several *Lactobacillus* strains respectively *Bifidobacterium* strains belonging to various species and it cannot readily be ascertained which of the deposited strains belongs to which species as written.. The correlation is unclear and should be specifically designated, for example, by inserting the appropriate species designation before the deposit number.

The rejection under double patenting is withdrawn in view of the proper terminal disclaimer presented.

Claims 1-10 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely *et al.* (EP 1020123) taken with Shields, Jr. *et al.* (U.S. Patent 6,156,355), Runge *et al.* (U.S. Patent No. 7,037,708), by Berggren *et al.* (WO/00/79072) and Brassart *et al.* (U.S. Patent No. 5,603,930) and further taken with Reddy (U.S. Patent No. 4,806,368)

The claims are directed to an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid included in an ingestible carrier and including yeast extract.

As discussed in previous Office actions, the cited references disclose an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

The references differ from the claimed invention in that the specific strains of claim 4 are not disclosed and in the provision of milk products, milk based fermented products such as yogurt.. However, Brassart *et al.* adequately demonstrates that at least strains CNCM I-1225 and CNCM I-1226 are old and well known in the art as probiotics. In addition the reference demonstrates that the composition is provided as a yogurt a milk-based fermented product. See, e.g., col. 3, lines 55-60.

With regard to the pharmaceutical carrier, it is noted that the product of Berggren is provided at least in tablet form. In addition, yogurt containing strain CNCM I-1225 comprises a pharmaceutical carrier.

Regarding the presence of yeast extract, it is noted that Reddy adequately demonstrates that *Lactobacillus* and *Bifidobacterium* compositions containing yeast extract are old and well known in the art. See, e.g., Col. 3, Table. The reference discloses the benefits of the yeast extracts components to the viability of the bacteria, for example as a source of B vitamins.

The concentrations discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of concentrations for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the products of Cavaliere Vesely *et al.*, Shields, Jr. *et al.*, Runge *et al.* and Berggren *et al.* by providing a composition comprising a photoprotective amount of probiotic strains CNCM I-1225 and CNCM I-1226 as suggested by the teachings of Brassart *et al.* for the expected benefit of providing a healthful composition comprising a probiotic strain known to have favorable effects against disease and carotenoids such as  $\beta$ -carotene known to have at least antioxidant effects.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

#### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In *re* Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In *re* Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Cavaliere Vesely *et al.*, Shields, Jr. *et al.*, Runge *et al.*, Berggren *et al.* are all directed to compositions comprising lactic acid probiotics and carotenoid or carotenoid derivatives even

though references do not teach that the composition can be used for photoprotection of the skin. However, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the cited compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112). In this regard, it is noteworthy that the claims are directed to a composition comprising "10<sup>-12</sup>% to 20% by weight of an unidentified carotenoid.. There is nothing on the record to indicate to what extent a composition comprising carotenoids at the lower end of the range recited will have the required effect.

As noted previously the addition of yeast extract to probiotic lactic acid compositions is well known in the art for its viability enhancement.

Regarding the arguments directed to strains CNCM I-1225 and I-1226, these arguments are only pertinent with respect to dependent claim 4, which is the only claim directed to specific strains. The claims as written are directed to a composition comprising at least one probiotic lactic acid bacterium in undisclosed amounts, at least one carotenoid in amounts as low as 1 x 10<sup>-12</sup> by weight and yeast extract in an undisclosed amount. Inasmuch as the crux of the teachings of the references is that compositions as claimed comprising probiotics closely related to the strains of interest are known in the art, one of ordinary skill in the art would have had compelling motivation to provide compositions containing known strains recognized to have beneficial properties with substances such as antioxidant carotenoids and nutritious yeast extract with a reasonable expectation of providing a product having outstanding nutritional properties and likely to enhance overall health, including that of the skin

Applicant's argue that the presently claimed oral composition includes an admixture of very specific constituents that surprisingly and unexpectedly elicit an enhanced effect or

response in respect of the photoprotection of the skin citing the Specification, page 14, lines 6-11. Yet the claims are directed to any lactic acid bacterial probiotic, with unidentified carotenoids added in a range that includes minuscule amounts.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

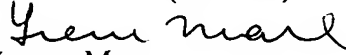
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

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Irene Marx  
Primary Examiner  
Art Unit 1651